Integrated Systems Health Engineering and Management (ISHEM) in Aerospace Forum

November 7-10, 2005

- NASA Quality Assurance Policy -

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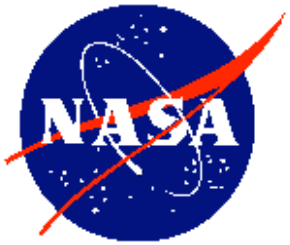
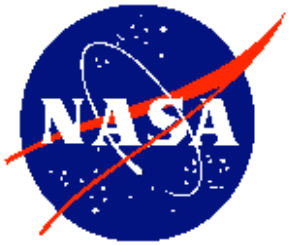


NASA missions cannot succeed
if requirements are not complied with

NASA personnel are not safe
if requirements are not complied with



Quality Assurance:

Discipline to ensure that requirements are complied with

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Risk Based:

- Designed and implemented to mitigate risk associated with noncompliance

  Risk = Likelihood and consequences of non-compliance, including the maturity, complexity, criticality, importance and cost of work performed, as well as past quality performance

- Attain confidence levels commensurate with severity of consequences incurred due to noncompliance

- 100% verification of critical product attributes

  Critical = Material characteristics, operating conditions or functional performance criteria that if not met can result in loss of life, serious injury, or loss of mission

- Continual re-evaluation and adjustment due to changes to risk factors

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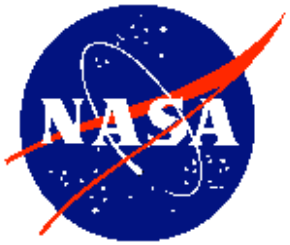

Proactive:

Pre-work assurance measures that provide increased confidence for the meeting of prescribed requirements

- **Pre-Award/Post-Award Surveys**
- **Document Control**
- **Training**
- **Workmanship Qualification Standards**
- **Supplier Outreach and Process Control Assurance**

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Continual improvement:

Achieve continual improvement through advocacy; awareness training; teaming and sharing of quality assurance tools, techniques and data; integration of quality assurance processes to prevent duplication of effort; and dissemination/implementation of lessons learned and best practices

- **NASA Quality Leadership Forum (QLF)**
- **NASA Joint Audit Planning Committee (JAPC)**
- **Americas Aerospace Quality Group (AAQG)**
- **International Aerospace Quality Group (IAQG)**
- **Conference on Quality in the Space and Defense Industries (CQSDI)**
- **Registrar Management Committee (RMC)**
- **Nadcap Special Process Accreditation**

Sharing Quality Data

NASA Air Force NRO Army
FAA MDA
NAVSEA
NAVAIR

GIDEP

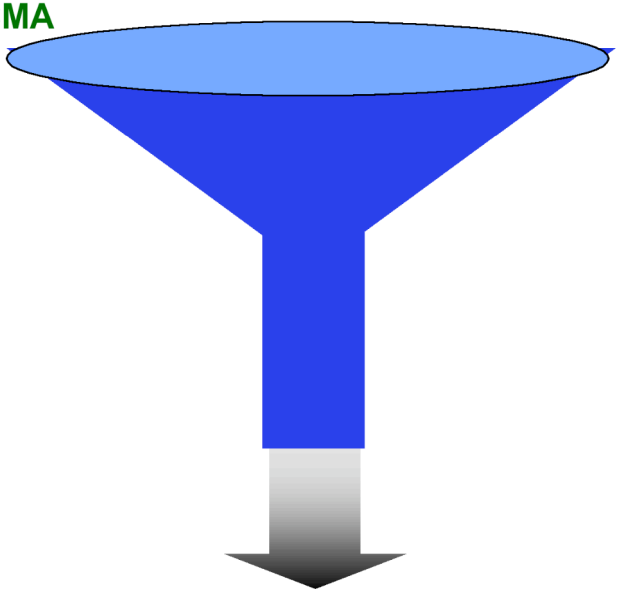
DCMA

Provides:

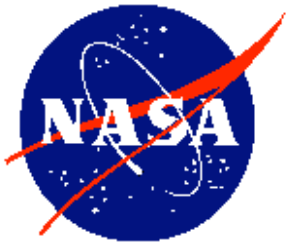
- Quality Leading Indicators
- Delivery Ratings
- Source Selection Tool

Accessed by:

- NASA Program Managers
- NASA Quality Assurance
- NASA Procurement
- Prime Contractors
- Other Govm't Agencies



Supplier Assessment System



Flow Down

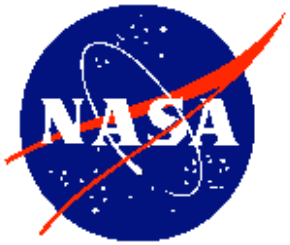
Flow applicable quality assurance requirements down to successive levels of the supply chain to ensure control of subtier suppliers and verification of safety/mission critical attributes at all levels of the supply chain

Recurrence Control

Provide for investigative and corrective actions upon discovery or notification of noncompliance

- **Investigative actions shall identify the proximate and root cause(s) of noncompliance and the scope/population of noncompliant items**

- **Corrective actions shall include the correction, replacement, repair, or authorized disposition of noncompliant items/conditions, implementation of preventive measures to eliminate the causes of noncompliance, and validation that implemented preventive measures have effectively eliminated recurrence of the noncompliant condition**



Communication

Ensure clear and mutual understanding of prescribed quality requirements among organizations responsible for contracting or assigning work, performing work, and assuring conformity of work

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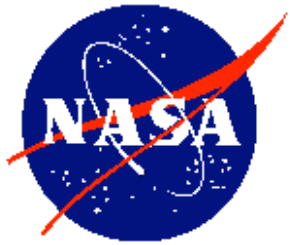
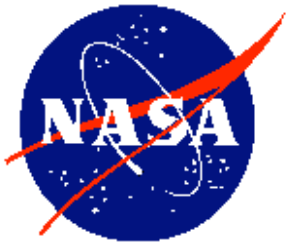


Competency

Be performed by persons that are competent on the basis of:

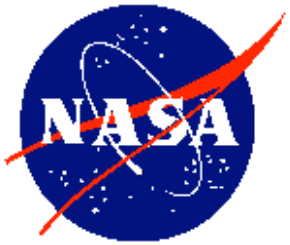
- **Demonstrated knowledge, skills, and experience related to quality assurance principles and practices, and related to the specific product, process, or attribute for which assurance is being provided**

- **Meeting formal certification or qualification requirements where prescribed in required/invoked documents or where deemed necessary to ensure personnel competency to perform specialized quality assurance functions**



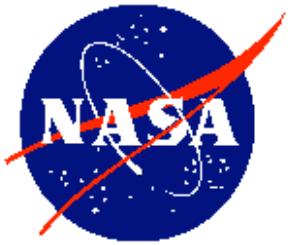
Independence

Be performed by persons that are not assigned direct responsibility for ensuring that cost or schedule objectives are met



Quality Data Analysis

Include the collection and analysis of quality data for the purpose of identifying and initiating resolution of problem areas (e.g., projects, products, processes, operations, organizations), common deficiency causes, nonconformance trends, defect anomalies, and process variations



Objective Quality Evidence

Be supported by records demonstrating compliance with technical/quality requirements. Records shall be legible, traceable to the applicable product, identifiable to the applicable requirement, and readily retrievable for requirement verification

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Quality System

Quality Requirements for Activities Performing Work					
	AS9100	ISO 9001	AS9003	FAR Inspection Clause(s)	Quality Clauses (ARP 9009)
Critical and Complex Work	X				X
Complex / Non-Critical Work		X			X
Critical / Non-complex Work			X		X
Non-Critical Work				X	

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Roadmap

1. **Establish Requirements**

2. **Assure Compliance with Requirements (Technical and Quality)**

2.A Organization Performing Work

Quality System Requirements

- **2.A.1 Prevention**
- **2.A.2 Detection/ Correction**

2.B Customer (Contracting Agent)

Quality Program Elements

- **2.B.1 Prevention**
- **2.B.2 Detection/ Correction**

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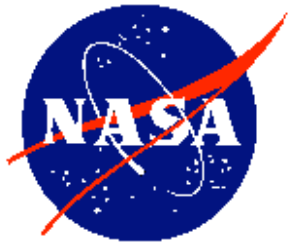
Government Quality Assurance

- Contract Review
- Pre-award Survey
- Document Review
- Product Assurance
- Quality System Audit
- Quality Data Evaluation
- Final Product Acceptance
- Nonconformance Reporting and Corrective/Preventive Action



Back-Up Slides

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Critical

- Loss of Life
- Serious personnel injury
- Loss of Mission
- Loss of Significant Mission Resource

Complex

Manufacture, Fabrication, Assembly, Testing, or Integration

of

Machinery, Equipment, or Sub-systems

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AS9100 Quality System

Quality Management System
- Documentation Requirements
  - Quality Manual
  - Control of Documents
  - Control of Records
- Configuration Management

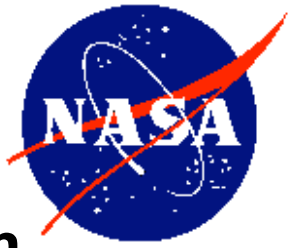
Management Responsibility
- Management Commitment
- Customer Focus
- Quality Policy
- Planning
- Responsibility, Authority and Communication
- Management Review

Resource Management
- Provision of Resources
- Human Resources
- Infrastructure
- Work Environment

Product Realization
- Planning of Product Realization
- Customer Related Processes
- Design and Development
- Purchasing
  - Purchasing Information
  - Verification of Purchased Product
- Production and Service Provision
  - Identification and Traceability
- Control of Monitoring & Measuring Devices

Measurement, Analysis and Improvement
- Monitoring and Measurement
  - Internal Audit
  - Processes
  - Product
- Control of Nonconforming Product
- Analysis of Data
- Improvement
  - Corrective Action
  - Preventive Action

- Quality Roadmap -



AS9003 Inspection and Test Quality System

- Management Responsibility
- Quality System
- Contract Review
- Design Control
- Document and Data Control
- Purchasing
- Control of Customer Supplied Product
- Product Identification and Traceability
- Process Control
- Inspection and Testing
- Control of Nonconforming Product
- Corrective Action
- Handling, Storage, Packaging, Preservation and Delivery
- Control of Quality Records
- Internal Quality Assessment
- Training
- Servicing
- Statistical Techniques

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Quality Contract Clauses

- Quality System
- Material Identification, Damage, Count
- Right of Access
- Flow Down Requirements
- Certificate of Compliance (C of C)
- Certificate of Compliance Raw Material
- Certificate of Compliance - Calibration
- Special Process Certification
- Calibration System
- Configuration Management System
- Change Authority
- Critical Processes
- Government Source Inspection (GSI)
- Contractor Source Inspection (CSI)
- First Article Inspection
- Nondestructive Inspection (NDI) / Nondestructive Test (NDT) Certification
- 100% Attribute Clauses
- Limited Operating Life Items
- Limited Life and Age Control (Shelf Life)
- Packaging Requirements
- Packaging Handling & Labeling
- Shipping Documents
- Nonconformance Reporting
- GIDEP
- Record Retention
- Electrical Wire and Cable Test Report
- EEE parts Date of Manufacture
- EEE Single Lot / Date Code
- Electrostatic Discharge (ESD) Protection Program
- High-Strength Fasteners
- Pressure Vessels
- Solvent Containers

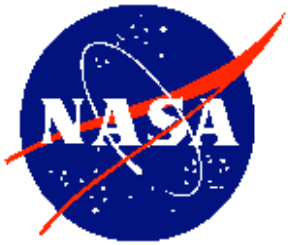
Contract Quality Clause Examples

Certificate of compliance- Raw materials

"Organization will include with each shipment the raw material manufacturer's test report (e.g., mill test report) that states that the lot of material furnished has been tested, inspected, and found to be in compliance with the applicable material specifications. The test report will list the specifications, including revision numbers or letters, to which the material has been tested and/or inspected and the identification of the material lot to which it applies. When the material specification requires quantitative limits for chemical, mechanical, or physical properties, the test report will contain the actual test …

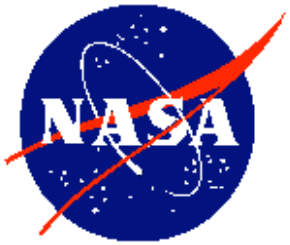
Calibration System

"The organization shall have a documented calibration system that meets the requirements of ISO 10012, "Quality assurance requirements for measuring equipment", or the "American National Standard Institute (ANSI)/National Conference of Standards Laboratories (NCSL) Z540-1, General Requirements for Calibration Laboratories and Measuring and Test Equipment".



Code of Federal Regulations: Part 287– Guidance on Federal Conformity Assessment

"Each agency should coordinate its conformity assessment activities with those of other appropriate government agencies and with those of the private sector to reduce unnecessary duplication."



FAR Inspection Clause

"The Contractor shall maintain an inspection system acceptable to the Government covering supplies under this contract and shall tender to the Government for acceptance only supplies that have been inspected in accordance with the inspection system and have been found by the Contractor to be in conformity with contract requirements."

Government QA Program Elements

- **Contract Review**
- Assurance that contracts contain necessary/appropriate quality requirements and clauses based on the criticality, complexity, maturity and cost of the product supplied, and based on organization quality history.

- **Pre-award Survey**
- Assessment of organization's quality system and capability to comply with contract requirements, including review/acceptance of organization's documented quality manual and associated quality system procedures. Performed prior to contact award for new organizations and organizations with poor quality history.

- **Document Review**
- Verification that quality system procedures and technical data/drawings are properly documented and compliant with contract requirements. Performed on a periodic basis and whenever substantive changes are made. Selection of documents based on criticality, complexity, and cost of product supplied; criticality of process/attribute documented by procedure/data/drawing; and quality history.

- **Product Assurance**
  - Physical examination, measurement, and non-destructive testing of products; witnessing of manufacturing, fabrication, assembly, integration, and test processes; and review of recorded data for conformance to requirements. Selection, sample size, and frequency based on the criticality, complexity, maturity, and cost of product supplied, and quality history.
  - Government Mandatory Inspection Points:

Quality System Audit

- Review of organization's quality system to validate compliance with invoked quality program requirements, including internally developed procedures and operating instructions. The quality system audit may be conducted as a single audit or as a combination of audits. For AS 9100 invoked quality systems, the review shall be performed at least annually. For AS 9003 quality systems, the review shall be performed no less than once every three years. The following quality system elements must be reviewed, as a minimum.

a. Personnel training, qualifications, and competence

b. Purchasing

- i. Supplier evaluation/selection
- ii Purchasing information and flow-down of technical/quality requirements
- iii Verification of Purchased Product

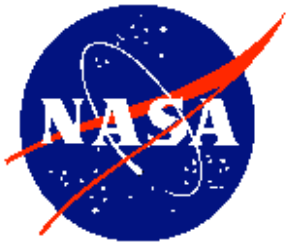
c. Quality Management System Documentation and Control of Documents

- d. Preservation of Product, and foreign object prevention, detection, and removal
- e. Calibration and Control of Monitoring, Measuring and Test Devices
- f. Product Identification, Traceability, and Identification of Inspection/Test Status
- g. Control of Nonconforming Product
- h. Monitoring and Measurement
- i. Internal Audit/Assessment
- ii. Monitoring and Measurement of Processes
- iii. Monitoring and Measurement of Product (Inspection and Testing)

i. Data Analysis

- j. Nonconformance Reporting and Corrective Action
- k. Configuration Management/Control
- l. Design and Development Control
- m. Production Control and Process Control

Government QA Program Elements



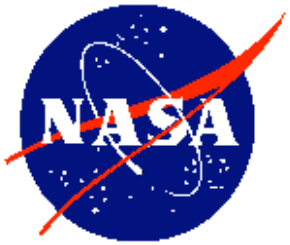
- **Nonconformance Reporting and Corrective/Preventive Action**
- **Documentation of customer identified technical and quality system non-conformances, and assurance of effective corrective/preventive action . Corrective action requests shall be elevated to the appropriate level of management based on problem criticality, recurrence, or non-responsiveness. As appropriate, based on the nature/criticality of the nonconformance, corrective action requests shall require identification of the root cause(s) of the nonconformity, scope of the nonconformity, remedial corrective actions concerning the product(s) found to be nonconforming, and long term preventive measures. As deemed necessary, based on the severity and history of the nonconformity, customer follow-up shall be performed to ensure effective accomplishment of corrective/preventive action.**

- **Quality Data Evaluation**
- **The collection, evaluation, and use of quality data to identify problem areas, trends, defect anomalies, process variations and process capabilities. Sources of data include organization generated metrics, customer identified non-conformities, and quality data reported by customer delegated representatives, or Government agencies. Data shall be evaluated at established periodic intervals for the purpose of:**
  - **Adjusting the frequency and content of customer oversight actions, including allocation of quality assurance personnel resources**
  - **Providing a basis for acceptance/rejection of the organization's quality system and written procedures**
  - **Notifying contracting/purchasing offices of significant quality problems**
  - **Providing a basis for understanding or recommending improvements to critical processes and materials that cannot be verified by inspection or test**
  - **Notifying the organization of problem areas and trends identified**

- **Subcontracted Work**
- **Customer source inspection of subcontracted work shall be performed as necessary to ensure that the organization maintains effective oversight of subcontractors, or where performance of mandatory inspection points at the subcontractor's facility is deemed in the customer's interest.**
- **Government inspection of subcontracted supplies or services shall be performed for Government Mandatory Inspection Points:**
  - **That can only be performed at the subcontractor's location**
  - **Where performance at a later point in time or at any other location would require uneconomical disassembly, destructive testing, or special required instruments/gauges/facilities only available at the subcontractor location**
  - **Where performance at any other location would destroy or require the replacement of costly special packaging**
  - **Where considerable cost to the Government or unacceptable delay in schedule would result from downstream identification of non-compliant products**

- **Final Product Acceptance**
- **Formal acceptance of delivered product based on:**
  - **Final product inspection**
  - **Validation that there are no outstanding corrective actions resulting from customer or organization identified nonconformances that affect acceptability of product**
  - **Validation that there are no outstanding engineering departures impacting acceptability of product, and that all applicable engineering departures have been approved by the proper technical authority**
  - **One-for-one accountability and validation that all GMIPs have been successfully accomplished**

NASA QUALITY LEADERSHIP FORUM (QLF)

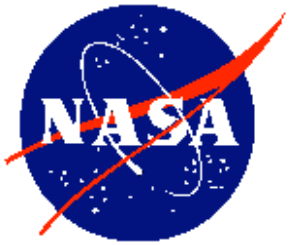


MISSION STATEMENT

The Quality Leadership Forum (QLF) is an aerospace forum that meets semiannually for the advancement of quality assurance practices. The principal objectives of the QLF are to:

- **Integrate quality approaches**
- **Standardize quality practices**
- **Resolve current problems**
- **Improve use of quality resources**
- **Define and analyze quality risks**
- **Communicate lessons learned**
- **Share best practices**
- **Improve quality processes**

What is the JAPC?



Joint Government – Industry Forum

- **Planning, coordinating, integrating supplier audits**
- **Sharing supplier quality data**
- **Resolving supplier quality issues**
- **Sharing best practices/ lessons learned**
- **Standardizing Auditing Practices**
- **Developing Agency-Wide Metrics**

Supplier Outreach Process Control Assurance Program

The SOPCA Program GOAL is to…

- *THANK Supplier's and their workforce*
  - **Recognize the company and outstanding individuals**
  - **Encourage Suppliers to be proactive**
- *SHARE lessons learned and best practices*
  - **Communicate expectations, successes, program issues**
  - **Receive feedback of Supplier's perspective**
- *PROVIDE tools, resources and awareness products*
  - **Websites: Quality Suppliers , Quality Leadership Forum**
  - **Training tools: Root Cause Analysis, Continuous Improvement, Audit best practices, process control training videos, etc.**
- *CAPTURE Supplier data to share within the Agency*
  - **NASA Supplier Information Surveys**
  - **Conduct Process Control visits; data used to address issues (if any) in a supportive manner.**

NASA Supplier Assessment System (SAS)

Goal: To provide a tool which will assist NASA Centers and other Government agencies in evaluating the ability of their suppliers to meet specified quality standards.

Objectives:

- Provide visibility into leading indicators of supplier quality
- Expand our knowledge base of supplier data and audit results
- Improve communication
- Decrease surveillance costs and enhance the use of Government resources
- Improve supplier relations with fewer audits/assessments
- Increase leverage with suppliers by sharing information across agencies
- Provide access to standardized audit tools